

REMARKS/ARGUMENTS

Claims 1-67 remain pending. All pending claims were previously rejected as allegedly being unpatentable for the cited art. Claims 68-71 have been cancelled pursuant to a restriction requirement. No claims have been amended or added. Reexamination and reconsideration of pending claims 1-67 are respectfully requested.

Claims 1, 3, 4, 6-12, 14-20, 23-27, 29-31, 33-36 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US patent number 6,048,342 in the name of Zucherman et al., in view of US patent number 4,834,757 in the name of Brantigan, and further in view of US patent publication number 2002/0016592 in the name of Branch et al. Claims 2, 13, 21-22, 63, and 66 were rejected under §103(a) as allegedly being unpatentable over a similar combination of the Zucherman '342 patent, the Brantigan '757 patent, and the Branch et al. '592 publication as applied above, here further in view of a Brantigan '327 patent. Claims 5 and 28 were rejected under §103(a) as allegedly being unpatentable over the same Zucherman '342 patent, Brantigan '757 patent, and Branch et al. '592 publication combination, further in view of Zucherman et al. publication 2001/0012938. Claims 37-41, 43-55, and 57-61 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over a combination of the Zucherman '342 patent, the Brantigan '327 patent, and the Branch et al. '592 publication. Claims 42 and 56 were rejected under §103(a) as allegedly being unpatentable over a similar combination of the Zucherman '342 patent, Brantigan '327 patent, and Branch et al. '592 publication, further in view of the Zucherman '938 publication. Claims 62, 64, 65, and 67 were rejected under §103(a) as allegedly being unpatentable over the Zucherman '342 patent, Brantigan '757 patent, and Branch et al. '592 publication, while claims 63 and 66 were rejected as allegedly being unpatentable over the combination of the Zucherman '342 patent, Branch et al. '592 publication, and Brantigan '757 patent, further in view of the Brantigan '327 reference. All of these rejections are traversed as follows:

Independent claim 1 recites the following elements:

1. *An implant adapted to be placed between spinous processes comprising:*

a body that includes a shaft; wherein the shaft is radiopaque;

a spacer rotatably mounted on the shaft; and

a tissue expander extending from the shaft;

wherein the tissue expander is at least in part radiolucent,

wherein the partially radiolucent tissue expander distracts the soft tissue and the spinous processes while not impairing the ability to view the spinous processes in an x-ray.

Hence, the implant of independent claim 1 includes a radiopaque shaft, along with a tissue expander extending from the shaft, with the tissue expander being at least in part radiolucent. Along with this specific combination of radiopaque and at least partially radiolucent structures, claim 1 explicitly recites that the radiolucent structure of the tissue expander allows soft tissue to be distracted without impairing viewing of the spinous process in an x-ray. Applicants respectfully submit that the cited references do not reasonably support a rejection of an *implant* including a radiopaque shaft and at least partially radiolucent tissue expander as recited by claim 1, much less one which allows soft tissue distraction while preserving the ability to view spinous processes in an x-ray.

As an initial matter, applicants note that exemplary structures and use of tissue expanders or distraction guides, as incorporated into an implant, are described throughout the originally filed specification for this application, including in paragraph 15 on page 5, which states that that exemplary tissue expander or distraction guide [(110)] can be seen in Figures 1A and 1B, and acts to distract the soft tissue in the spinous processes when implant 100 is inserted between adjacent processes. In that particular embodiment, guide 110 has an expanding cross section from a distill end 111 to (as seen in the drawings) an interface between the tissue expander and shaft 102.

Referring now to the differences between the cited art and the claimed invention, the office action mailed on May 7, 2007, on page 3, acknowledges that the Zucherman et al. reference does not disclose a tissue expander being radiolucent. Nonetheless, the office action asserts that "Brantigan '757 teaches the incorporation of radiolucent materials for improved x-ray visualization of the device [see column 1, lines 31-36]". Applicants respectfully submit that this alleged teaching of the Brantigan reference is insufficient to support a rejection of the specific combination of elements included in the implant of claim 1. More specifically, nothing in this alleged interpretation of the Brantigan '757 patent even remotely suggests the use of a radiopaque shaft and at least partially radiolucent tissue expander extending from that shaft. Furthermore, the actually disclosure included in column 1, lines 31-36 of the Brantigan '757 patent is reproduced below:

A still further specific feature of the invention is the provision of plugs which are radiolucent for *improved x-ray visualization of the bone healing post operatively*.

The paragraph breaching columns 6 and 7 of the Brantigan '757 patent explains additional details which help clarify the purpose of the radiolucent material in that device:

The paragraph beginning on line 66 in column 6 of the '757 patent and ending on line 5 in column 7.

Per this disclosure, the reason for including radiolucent material in the Brantigan '757 device is to allow monitoring of bone growth into the structure, and there is no articulated rationale for transferring this bone growth-based radiolucent property of the Brantigan implant to selectively be applied to the tissue expander structure of the implant in claim 1. Lastly, contrary to the analysis in the office action, incorporation of radiolucent materials does not generally improve x-ray visualization "of the device," as radiolucent materials do not show up on an x-ray.

Regarding the Branch et al. '592 publication, applicants note that that reference describes an inter-body fusion graft and associated instrumentation. Per paragraph 9 of the Branch et al. '592 publication, an implant holder may be used to grip and implant the fusion graft, with the gripping head of the implant holder having a pin including at least a radiopaque

portion. Applicants respectfully submit that the disclosure of Branch et al., particularly that regarding the use of an implant delivery **tool** having a radiopaque structure, falls far short of the specific structural elements recited by independent claim 1. In fact, in the description of the method for implantation of the Branch et al. implant appearing from paragraphs 179-187 of the Branch et al. '592 publication, distraction for insertion of the Branch et. al. fusion graph appears to largely be effected using a series of gradually increasing diameter distracters 370 [(see paragraph 182)] and a protective sleeve 510 [(see paragraph 184)] inserted using a mallet. These distraction structures are then removed in the Branch et. al. methodology. Hence, any proposed combination of the radiolucent bone growth monitoring implant of Brantigan with the radiopaque implantation tool of Branch et. al. so as to result in the radiopaque shaft and at least partially radiolucent tissue expander included in the implant of claim 1 appears to be generally contrary to the actual disclosures in the references themselves.

Regarding independent claim 19, that claim recites an implant having a radiopaque shaft and a tissue expander which is at least in part radiolucent. Independent claim 37 recites an implant having a radiopaque shaft and a tissue expander which is also at least in part radiolucent. Independent claims 47 and 62 similarly recite related structures. Hence, each of the independent claims is allowable over the Zucherman et. al. '342 patent, Brantigan '757 patent, and Branch et. al. '592 publication for many of the reasons given above regarding claim 1.

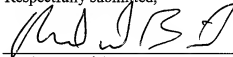
Regarding the Brantigan '327 reference, that document is cited regarding the use of a particular material in an implant. The Zucherman et. al. '938 publication is cited as disclosing an off-center bore in a spacer. As the cited portions of these references has not been shown to overcome the shortcomings of the references addressed in detail regarding claim 1, applicants respectfully request that the rejections of all claims be removed, and that the claims be allowed.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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